IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

In re POZEN SECURITIES LITIGATION	))	MASTER FILE NO. 1:04CV00505 CLASS ACTION

MEMORANDUM OPINION

BULLOCK, District Judge

Lead Plaintiff Emanuel Klibaner and all investors similarly situated ("Plaintiffs") bring this putative class action against Pozen, Inc., and John R. Plachetka, Pozen's Chairman, President, and Chief Executive Officer, (together, "Defendants") alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated under Section 10(b) (17 C.F.R. § 240.10b-5). Before the court is Defendants' motion to dismiss the complaint for failure to state a claim under the Private Securities Litigation Reform Act ("PSLRA") (15 U.S.C. § 78u-4 et seq.). For the reasons set forth below, Defendants' motion will be denied.

FACTS

Pozen, Inc., is a pharmaceutical company incorporated in Delaware with its principal place of business in Chapel Hill, North Carolina. The company has developed the drugs MT 300 and

MT 100 for the treatment of migraine pain and related symptoms. Pozen submitted New Drug Applications ("NDA") for MT 300 and MT 100 to the United States Food and Drug Administration ("FDA") on December 17, 2002, and July 31, 2003, respectively. The FDA rejected the MT 300 NDA on October 20, 2003, and the MT 100 NDA on May 28, 2004. Pozen's stock dropped appreciably in response to each rejection, and on June 4, 2004, the first of five class action lawsuits was filed, alleging fraud in numerous public statements in which Defendants discussed the effectiveness and prospects of FDA approval of MT 100 and MT 300. The cases were consolidated on July 28, 2004, and Emanuel Klibaner was named lead plaintiff on November 4, 2004. The class has not been certified.

During the putative class period from October 4, 2002, to May 28, 2004, Defendants issued several public statements affirming the efficacy of MT 100 and MT 300 in treating the symptoms of migraine headaches. Defendants also issued statements expressing their expectation that the FDA would approve the drugs for sale in the United States. Plaintiffs contend that statements that the drugs were effective were false because both MT 100 and MT 300 failed to demonstrate effectiveness, as measured by long-standing FDA protocols, in Pozen's clinical studies. Plaintiffs also argue that Defendants' assertions that they believed the FDA could or would approve the

drugs were false because the FDA always applies the same standard to new migraine medicines, and Defendants knew the drugs had failed to meet it. Defendants deny the falsity of the various statements and contend that Plaintiffs have failed to establish a prima facie case of securities fraud under the PSLRA.

DISCUSSION

It is a violation of Section 10(b) of the Exchange Act for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Rule 10b-5, promulgated under Section 10(b), further provides that:

> It shall be unlawful for any person . . . [t]o make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, . . . in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. To state a claim of fraud under Section 10(b) and Rule 10b-5, a plaintiff must demonstrate that "(1) the defendant made a false statement or omission of material fact (2) with scienter (3) upon which the plaintiff justifiably

relied (4) that proximately caused the plaintiff's damages." Phillips v. LCI Int'l, Inc., 190 F.3d 609, 613 (4th Cir. 1999).

Allegations of securities fraud also must meet the heightened pleading standards of the PSLRA. The PSLRA requires that the complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts upon which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The statement or omission at issue must be based in fact, demonstrably true or false, and material to a reasonable investor. See Ottmann v. Hanger Orthopedic Group, Inc., 353 F.3d 338, 342-43 (4th Cir. 2003).

In addition, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). See Phillips, 190 F.3d at 621 (noting that the complaint must contain "a substantial factual basis in order to create a strong inference that the defendant acted with the required state of mind." (internal quotations omitted)). The scienter element is met when a plaintiff pleads facts demonstrating the defendant's intentional or reckless conduct.[1] Ottmann, 353 F.3d at 344. A

[1]The Fourth Circuit defines recklessness as "an act 'so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading

"flexible, case-specific analysis" guides the court in determining the sufficiency of a plaintiff's scienter allegations. Id. at 345. A complaint that fails to comply with these heightened pleading requirements must be dismissed. See 15 U.S.C. § 78u-4(b)(3)(A). Defendants seek to dismiss Plaintiffs' complaint for failure to plead falsity with particularity, failure to demonstrate that the allegedly false statements were material, and failure to plead scienter under the PSLRA.

I. MT 300

MT 300 is an injectable drug designed to treat the symptoms of migraine headaches. Pozen pursued FDA approval for MT 300, a process that requires at least two clinical studies demonstrating, among other qualities not at issue here, MT 300's effectiveness against migraine pain, known as the primary endpoint of the studies, as well as effectiveness in treating the secondary endpoints of nausea and sensitivity to light and sound. Pozen conducted its clinical studies using a two-hour protocol which required MT 300 to show results statistically superior to a placebo by or at two hours after patients took the medicine. This two-hour benchmark applied to the primary and secondary

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the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" Phillips v. LCI Int'l, Inc., 190 F.3d 609, 621 (4th Cir. 1999) (quoting Hoffman v. Estabrook & Co., Inc., 587 F.2d 509, 517 (1st Cir. 1978)).

endpoints of the studies. Notably, the two-hour protocol adopted by Pozen was accepted by the FDA, with which the company conferred in designing the clinical studies.

On October 4, 2002, Pozen issued a press release, the headline of which stated that "Pozen's Second Pivotal Study for MT 300 Hits Primary But Not Secondary Endpoints." The press release describes the primary endpoint as "sustained pain relief," and defines that term as "patients achieving pain relief within 2 hours of dosing and neither relapsing nor using rescue medicine over the next 22 hours." The secondary endpoints are identified as "nausea and sensitivity to light and sound." The measure against which the secondary endpoints were assessed is not expressly defined in the press release.

The press release does state, however, that:

> The analysis of the data indicated that . . . MT 300 was not statistically superior to placebo for the secondary symptoms of migraine over the 2-hour post dose period. Further analysis of the data indicated that a statistically significantly greater number of patients treated with MT 300 than placebo had <u>sustained relief</u> of sensitivity to light (26% vs. 17%) and sound (33% vs. 24%) and the difference between MT 300 and placebo in the sustained relief of nausea was marginally statistically significant(36% vs. 29%; p=0.075).

Defs.' Br. Supp. Mot. Dismiss, Ex. D (emphasis added). Plaintiffs contend that, in stating that MT 300 demonstrated "sustained relief" of the secondary endpoints, Defendants falsely

stated that the drug was effective in treating those symptoms of migraine within the two-hour time limit.

Pozen's drafting of the press release all but invited such a claim. In reference to the primary endpoint of relief of migraine pain, Pozen defined the term "sustained relief" as "relief within 2 hours of dosing" with no relapse over the next 22 hours. That is, Pozen defined a showing of "sustained relief" of pain as satisfying the two-hour protocol used in the clinical studies. Pozen then applied a different definition to the term "sustained relief" when used in relation to the secondary endpoints. In that context, Pozen intended the term to mean relief at times more than two hours after dosing. Although poorly written (or, perhaps, artfully written), a moderately careful reading of the press release makes the different usage clear: the release states that MT 300 failed to achieve the secondary endpoints within two hours, then states that "further analysis" of the data showed "sustained relief" of those endpoints, and, finally, the release describes Pozen's efforts to convince "the [FDA] that a sustained relief analysis of the secondary symptoms of migraine is a more clinically meaningful analysis than simply an assessment of a symptom at an isolated time point," i.e., at two hours.

Use of the same term with different definitions within a single public statement could undoubtedly confuse some investors.

The securities laws, however, while placing significant burdens on issuers to make accurate and complete public disclosures, also place the minimal burden on investors to act reasonably. See, e.g., Phillips, 190 F.3d at 613 and Ottmann, 353 F.3d at 343 (citing Longman v. Food Lion, Inc., 197 F.3d 675, 682 (4th Cir. 1999)). Examined in the context of the entire press release, the statement Plaintiffs complain of is vague, but its meaning is discernable. Alternatively, if given the meaning Plaintiffs attribute to it, the statement lies in direct conflict with other, unambiguous statements to the contrary within the same press release. Under either reading, reliance on the identified statement for the proposition that MT 300 satisfied the two-hour protocol for the secondary endpoints is not justifiable and such a statement cannot be material to the reasonable investor. See Phillips and Ottmann, supra. Plaintiffs' claim that the October 4, 2002, press release includes false or misleading statements must, therefore, be dismissed.

Plaintiffs' remaining claims related to MT 300 are based on three press releases, dated December 17, 2002, March 13, 2003, and September 4, 2004, in which Pozen "touted" various events related to the drug. Although Plaintiffs complain primarily of statements within those press releases that express Pozen's confidence in the effectiveness of MT 300 while failing to state that MT 300 did not meet the two-hour protocol for the secondary

endpoints, the true problem presented by the press releases is the implication that MT 300 was approvable by the FDA.

Plaintiffs have alleged that the two-hour protocol was both well established and universally applied by the FDA to assess all endpoints of new migraine drugs. Plaintiffs cite earlier FDA decisions on migraine drugs, the FDA's documented NDA process, and standards adopted by an international scientific board for assessing the efficacy of migraine medicine. Defendants dispute Plaintiffs' characterization of the FDA's use of the two-hour rule as immutable, and cite other drug studies applying a purportedly different standard. That issue is not resolvable on the record currently before the court, although Plaintiffs have offered a sufficient factual basis for the allegation that the two-hour rule was the norm applied by the FDA to survive Defendants' motion to dismiss.

Whether the FDA universally applied the two-hour protocol without exception is, however, likely beside the point. The record clearly establishes that Pozen and the FDA agreed, prior to the initiation of the clinical studies, that MT 300's effectiveness, and thus its approvability, would be determined using the two-hour protocol. Similarly, Defendants' knowledge that the two-hour measure applied, and that MT 300 failed, in part, to meet it, is indisputable, as Pozen's October 4, 2002, press release makes clear. The contention that Defendants'

subsequent statements implying the approvability of MT 300 are, therefore, false and misleading, is adequately pled.

Defendants contend that the two-hour protocol was generally subject to modification, and, as they stated in the October 4, 2002, press release, that the company was in specific discussions with the FDA to apply some other standard to MT 300 in regard to the secondary endpoints. Defendants also correctly note that "mere expressions of optimism from company spokesmen" and "projections of future performance not worded as guarantees are generally not actionable." Raab v. General Physics Corp., 4 F.3d 286, 290 (4th Cir. 1993). But Defendants fail to acknowledge that "in a securities fraud case, a statement of opinion may be a false factual statement if the statement is false, disbelieved by its maker, and related to matters of fact which can be verified by objective evidence." Nolte v. Capital One Fin. Corp., 390 F.3d 311, 315 (4th Cir. 2004) (citing Longman v. Food Lion, Inc., 197 F.3d 675, 683 (4th Cir. 1999) and Virginia Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1093 (1991)).

MT 300 failed to demonstrate the effective treatment of the secondary symptoms of migraine using the very measure agreed upon by Pozen and the FDA prior to the initiation of the clinical studies. If Defendants had a reasonable expectation, something more than a blind hope, that the FDA would apply a standard other than the previously agreed upon two-hour protocol in assessing

MT 300's effectiveness, then the press releases may be protected "expressions of optimism." The FDA's eventual adherence to the two-hour protocol, and the resulting denial of approval for MT 300, would not change that presumption. If, on the other hand, Defendants lacked any reasonable basis for believing that the FDA would relax the two-hour protocol, their statements touting the effectiveness and implying the approvability of MT 300 are false factual statements--they are false statements of opinion that could not have been believed by Defendants. Discovery will permit Defendants to produce any records or documentation demonstrating a reasonable basis for expecting the FDA to use a measure other than the agreed upon two-hour protocol. In this context, it is doubtful that evidence showing that the two-hour protocol was not universally applied by the FDA will be determinative of the outcome. Instead, Defendants must produce evidence of some statement or indication by the FDA that the agency would at least consider Defendants' request to abandon the two-hour measure agreed upon at the outset of the clinical trials.[2]

[2]Plaintiffs cannot be expected to produce evidence indicating the absence of such communications at this stage of the proceedings. See Keeney v. Larkin, 306 F. Supp. 2d 522, 528 (D. Md. 2003) (noting that under the PSLRA, Plaintiffs are not required to plead "detailed evidentiary matter" or "set forth facts which, because of the lack of discovery, are in the exclusive possession of the Defendants.")

II. MT 100

MT 100 is an oral migraine treatment that combines two existing drugs into a single dose. As in the case of MT 300, Pozen's clinical studies were designed, in consultation with the FDA, to gauge the effectiveness of MT 100 against the two-hour protocol for the endpoints of migraine pain, nausea, and sensitivity to light and sound. Because MT 100 is a "combination drug," the FDA imposes the further requirement that the drug demonstrate superiority over each of its component drugs acting alone. Pozen conducted numerous clinical studies of MT 100 and the drug met all relevant endpoints in a single study only once. The FDA requires new drugs to do so in two separate studies. Nevertheless, Pozen repeatedly expressed confidence and the "belief" that the FDA would approve MT 100. This belief was based on Pozen's assumption that the FDA would, essentially, cherry-pick from Pozen's numerous studies those results demonstrating success for a given endpoint while disregarding the failures, and doing so from enough studies such that each endpoint was eventually satisfied. Pozen's declarations that MT 100 was effective were also based on a method of statistical analysis that differed from that approved by the FDA in designing the studies, at least in regard to some endpoints.

When the FDA denied approval of MT 100 on May 28, 2004, Pozen expressed surprise that the FDA rigidly applied the

two-hour protocol and the requirement that all endpoints be met in a single study twice, and that the FDA rejected Pozen's "refined" statistical analysis, which differed from that agreed upon in earlier stages of the NDA process. Pozen further stated that it had reason to believe, based on discussions with the FDA, that there would or could be some flexibility in each of those points of analysis. As in the case of MT 300, if Pozen had a reasonable basis for such expectations, then the falsity of the numerous statements identified in the complaint will be difficult to prove. Plaintiffs have demonstrated, however, through the full text of the FDA's letter to Pozen rejecting the MT 100 NDA, that the FDA warned Pozen as early as March 2002 that the "refined" statistical analysis Pozen applied in comparing MT 100 to naproxen, one of its component drugs, was not acceptable. Plaintiffs have adequately alleged that Pozen's subsequent public pronouncements stating or implying that MT 100 was effective and/or approvable were false or misleading. Plaintiffs have also adequately alleged that Defendants made such statements with scienter. Defendants' motion to dismiss must, therefore, be denied.

CONCLUSION

With the exception of the October 4, 2002, press release, Plaintiffs have adequately alleged the falsity of the identified statements issued by Defendants. Plaintiffs have also adequately alleged that Defendants made such statements with scienter. Defendants' motion to dismiss for failure to state a claim under the PSLRA will be denied.

An order in accordance with this memorandum opinion shall be entered contemporaneously herewith.

United States District Judge

August 30, 2005